

REMARKS

I. Summary of the Office Action

Claims 108-119, 143-145, and 147-150 were pending in this application. Of these claims, claims 115-119 are withdrawn as being directed to a non-elected species.

Claims 144 and 145 were objected to as being dependent upon a rejected base claim, but being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 108-114, 143, and 147-150 were rejected under 35 U.S.C. § 102(e) as being anticipated by Stevens et al. Patent No. WO 96/32882 (hereinafter "Stevens").

Claims 108-110, 112, 114, and 143 were rejected under 35 U.S.C. § 102(e) as being anticipated by Sideris U.S. Patent No. 5,433,727 (hereinafter "Sideris").

Claims 108-110, 112, 114, and 143 were rejected under 35 U.S.C. § 102(e) as being anticipated by Lesh et al. U.S. Patent No. 6,152,144 (hereinafter "Lesh").

Claims 111, 113, and 147-150 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sideris.

Claims 111, 113, and 147-150 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lesh.

Claims 108-114, 143, and 146-150 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kazuyuki et al. Patent No. EP 1013227 (hereinafter "Kazuyuki") in view of Das U.S. Patent No. 5,334,217 (hereinafter "Das").

II. Summary of Applicants' Reply

Applicants have amended claims 108 and 143 to more particularly define the present invention. The claim amendments are fully supported by the application as originally filed and therefore do not add new matter. For example, support for these amendments may be found at page 7, line 26 through page 10, line 23 of applicants' specification. The rejections of applicants' claims are respectfully traversed.

III. Applicants' Reply

A. The 35 U.S.C. § 102(e) Rejections

The Examiner rejected claims 108-114, 143, and 147-150 under 35 U.S.C. § 102(e) as being anticipated by Stevens. The Examiner rejected claims 108-110, 112, 114, and 143 under 35 U.S.C. § 102(e) as being anticipated by Sideris or alternatively Lesh (*see* Office Action, pages 3-5). Applicants respectfully traverse these rejections.

Applicants' invention, as defined by amended independent claim 108, comprises a medial portion and first and second sets of fingers which are formed from the same material as the medial portion. For example, as shown in FIGS. 1 and 2, the device may be formed from a hollow tube. The first and second sets of fingers are capable of extending substantially radially outward from the axis of the medial portion. The first set of fingers is unconnected to the second set of fingers at the radially outward ends, and is spaced an axial distance apart from the second set of fingers on the axis of the medial portion (*see* specification, FIGS. 1-5; and page 7, line 26 through page 10, line 23).

Stevens refers to a tubular device for sealing a penetration in the heart (*see* Stevens, Abstract). The tubular device includes a frame and a flexible patch material. The frame is made up of a hub and a plurality of spokes or struts coupled to the hub. For example, FIG. 25A shows struts 252 and 260 coupled to hub 250. Hub 250 "is a rigid material such as stainless steel" while struts 252 and 260 "are flexible, resilient wires of Nitinol (or other material exhibiting similar super-elastic characteristics)" (*see* Stevens, page 6, line 21 through page 7, line 7). Applicants respectfully submit that since the hub (i.e., the "medial portion") and the plurality of struts (i.e., the "first set and second sets of fingers") are made of different materials and coupled together, they cannot be said to be "formed from a same material" as required by claim 108. Rather, the hub and the plurality of struts are distinct components that are coupled together. Accordingly, Stevens does not show or suggest applicants' amended independent claim 108.

Sideris refers to a centering button device for occluding large heart defects (*see* Sideris, Abstract). The centering button device 10 includes an occluder 11 that is connected to a button loop 12 and a counter-occluder 14. In particular, the occluder 11 is made of foam 16 and a wire skeleton 18. The button loop 12 consists of a small loop 20, a radiopaque button 22, a middle loop 24, and a first loop 26 which is

sutured to the occluder 11. The counter-occluder 14 is sutured to wire skeleton 18 (*see* Sideris, FIGS. 1-4; and column 4, lines 20-50). As seen in column 4, lines 44-46 of Sideris, the counter-occluder 14 (i.e., the "first set of fingers") is connected to the wire skeleton 18 (i.e., the "second set of fingers"). Therefore, even if the counter-occluder 14 and the wire skeleton 18 were considered to be sets of fingers, they cannot be considered "unconnected . . . at the radially outward ends," as specified in applicants' independent claim 108. Moreover, since the two structures are connected, they cannot be said to be "spaced an axial distance apart" as also recited by applicants' independent claim 108.

Although applicants disagree with the Examiner's rejection in view of Sideris, applicants have amended independent claim 108 to recite that the first and second sets of fingers are "formed from a same material." As described above with respect to Sideris, the first loop 26 of the button loop 12 is sutured to the occluder 11 (*see* Sideris, column 4, lines 39-40). Therefore, even if the counter-occluder 14 and the wire skeleton 18 were considered to be sets of fingers, they would not be formed from the same material as the button loop 12 (i.e., the "medial portion"), as recited by amended independent claim 108. Instead, the counter-occluder 14, the wire skeleton 18 and the button loop 12 are separate structures that are sutured together. Thus, Sideris does not show or suggest applicants' amended independent claim 108.

Lesh refers to a device for occluding a body cavity, particularly the left atrial appendage of a heart (*see* Lesh, Abstract). The device includes an occluding member 11 that is secured to a retention member 12 by a hub 16 (*see* Lesh, FIGS. 1-3; and column 7, lines 31-43). In one embodiment, the retention member 12 has a shaft 28 and radially extending members 29 which anchor the shaft 28 and the occluding member 11 to tissue (*see* Lesh, FIGS. 3A and 3B; and column 8, lines 29-36). Lesh's shaft 28 (i.e., the "medial portion") is connected to the occluding member 11 (i.e., the "first set of fingers") by a hub 16 (*see* Lesh, column 7, lines 31-43). Thus, even if the occluding member 11 were considered to be a set of fingers, it would not be formed from the same material as shaft 28, as required by applicants' independent claim 108. Lesh therefore also does not show or suggest applicants' amended independent claim 108.

According to applicants' specification, forming first and second sets of fingers from the same material as a medial portion is beneficial for many reasons. First, "[m]anufacture of the connector or plug structures . . . is greatly facilitated." Moreover, the fingers are "integral at all times, and there is no need to attempt to assemble the

relatively small fingers" (*see* specification, page 15, lines 3-16). Applicants respectfully submit that Stevens, Sideris and Lesh do not show or suggest these features or advantages.

For at least the foregoing reasons, applicants submit that claim 108 is allowable over Stevens, Sideris and Lesh. Dependent claims 109-114, 143, and 147-150, which contain all the limitations of allowable claim 108, are allowable for at least the same reasons. Applicants respectfully request, therefore, that the 35 U.S.C. § 102(e) rejections of these claims be withdrawn.

B. The 35 U.S.C. § 103(a) Rejections

The Examiner rejected claims 111, 113, and 147-150 under 35 U.S.C. § 103(a) as being unpatentable over Sideris. The Examiner rejected claims 111, 113, and 147-150 under 35 U.S.C. § 103(a) as being unpatentable over Lesh. The Examiner also rejected claims 108-114, 143, and 146-150 under 35 U.S.C. § 103(a) as being unpatentable over Kazuyuki in view of Das (*see* Office Action, pages 6-8). Applicants respectfully traverse these rejections.

As shown above, neither Sideris nor Lesh shows or suggests first and second sets of fingers that are formed from the same material as a medial portion, as recited by applicants' amended independent claim 108. Applicants respectfully submit that neither Kazuyuki nor Das make up for the deficiencies in Sideris and Lesh.

Kazuyuki refers to a closure device and a catheter assembly for closing or repairing endocardiac or vascular defects (*see* Kazuyuki, ¶ 0001). The closure device includes a closure member 1, a fixing member 2 for fixing the closure member 1 to tissue, and a connecting member 3 for holding the closure member 1 and the fixing member 2 in close proximity of one another. In particular, the connecting member 3 is fixed at one end to the fixing member 2 and at the other end to the closure member 1 (*see* Kazuyuki, ¶ 0022). Since the fixing member 2 (i.e., the "first set of fingers") and the closure member 1 (i.e., the second set of fingers") are fixed to the connecting member 3 (i.e., the "medial portion"), they are not formed from the same material as the connecting member 3, as recited by independent claim 108. Thus, Kazuyuki does not show or suggest applicants' amended independent claim 108.

Das refers to a closure device with a pair of occluding disks that are attached to one another (*see* Das, column 3, lines 6-23). As shown in FIGS. 3-5, each

disk includes a membrane 22, 32 of any desired shape which is attached to a respective frame 24, 34 by any suitable means (*see* Das, column 4, lines 61-67; and column 5, lines 21-40). Nowhere does Das show or suggest first and second sets of fingers that formed from a same material as a medial portion, as required by applicants' amended independent claim 108. Thus, Das also does not show or suggest applicants' amended independent claim 108.

Therefore, Sideris, Lesh, Kazuyuki and Das, whether taken alone or in combination, do not show or suggest all the features recited by applicants' claim 108.

For at least the foregoing reasons, applicants submit that claim 108 is allowable over Sideris, Lesh, Kazuyuki and Das. Dependent claims 109-114, 143, and 147-150, which contain all the limitations of allowable claim 108, are allowable for at least the same reasons. Applicants respectfully request, therefore, that the 35 U.S.C. § 103(a) rejections of these claims be withdrawn.

IV. Conclusion

In view of the foregoing, claims 108-114, 143-145, and 147-150 are allowable over the prior art of record. This application is therefore in condition for allowance. Reconsideration, rejoinder of withdrawn claims 115-119, and allowance are respectfully requested.

Respectfully submitted,

/Baaba Andam/

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